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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 00D–1455]**

# Draft Guidance for Industry; Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice of a panel recommendation to reclassify totally implanted spinal cord stimulators from class III (premarket approval) to class II (special controls). If this device is reclassified, this draft guidance document will serve as the special control for the reclassified device. This guidance is neither final nor in effect at this time.

**DATES:** Submit written comments on the draft guidance by October 30, 2000.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief'' to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified



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with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Russell P. Pagano, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice of a panel recommendation to reclassify totally implanted spinal cord stimulators from class III (premarket approval) to class II (special controls). If this device is reclassified, this draft guidance document will serve as the special control for the reclassified device.

## II. Significance of Guidance

This draft guidance document represents the agency's current thinking on special controls for totally implanted spinal cord stimulators for pain relief. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

## III. Electronic Access

In order to receive the draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief'' via your fax machine,

call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1179 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

**IV. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by [*insert date 30 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the

heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/21/00
August 21, 2000

Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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